



Zabalafin Hydrogel for Molluscum Contagiosum: Emerging Evidence and Future Therapeutic Perspectives

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Received: 24 August, 2026; Revised: 2 September, 2026; Accepted: 13 September, 2026

Keywords: Pediatrics, Molluscum Contagiosum, Topical Therapy

Dear Editor,

This letter provides a narrative commentary on emerging topical approaches to molluscum contagiosum (MC), informed by a focused review of recently published literature and publicly available information on an investigational product in early clinical development. It is not a systematic review, and it presents no original patient data, refractory-case series, or biomarker results. Because this letter relies on published literature and publicly available developer information rather than our own cases, no patient photographs are included. The objective is to summarize what is currently known and unknown about Zabalafin Hydrogel for MC, situate it alongside established and recently approved therapies, and outline the evidence needed to define its clinical role.

Molluscum contagiosum is a benign but highly contagious viral skin disease caused by molluscum contagiosum virus (MCV), a member of the poxvirus family. Reported estimates suggest that it accounts for approximately 1% of dermatologic diagnoses worldwide, and an increasing incidence has been described, although figures vary by population and setting (1). The disease disproportionately affects children, young sexually active adults, and immunocompromised patients; one review reports that children are affected approximately 9 times more often than adults (1).

Immunity to MCV appears to vary across populations. In published studies, anti-MCV seropositivity has ranged from approximately 6% to 30% and has generally been higher in adults than in children, which may partly explain the lower frequency of clinical infection in adults. These figures are derived from specific study cohorts and should not be interpreted as universal, population-level estimates

(2). Despite this pattern, the United States Centers for Disease Control and Prevention notes that people can be infected with MCV more than once (3).

In people with normal immune function, MC lesions typically resolve spontaneously within 6 months to 1 year, although resolution can take longer (3). Because the clinical presentation is distinctive, diagnosis is almost always based on visual examination alone, without laboratory confirmation. Lesions present as discrete or clustered papules, generally 2 to 5 mm in diameter, that are flesh-colored or pink and have a characteristic dimpled (umbilicated) center. In children, lesions most often occur on the face, trunk, and limbs, whereas in sexually active young adults, they tend to appear in the genital area, reflecting transmission through sexual contact. Associated problems can include pruritus, eczematous skin changes, and secondary bacterial infection.

Current Management: Observation, Procedures, and Approved Topical Options

For many immunocompetent children, observation is a reasonable strategy because lesions commonly resolve spontaneously (3). When active lesion removal is desired, physical destruction of lesions via cryotherapy or curettage remains widely used, with well-established efficacy. Reported clearance rates in published trials range from 71% to 100% for cryotherapy and 70% to 80% for curettage, and both continue to have an accepted role in current clinical practice (4). Their principal drawbacks are practical rather than related to efficacy: they require multiple in-person visits, cause pain, and are often poorly tolerated by children, who account for most MC cases, largely because of procedural fear and discomfort (4). These practical

limitations, rather than any established shortfall in clearance rates, are the main driver of interest in nondestructive topical alternatives.

Topical options are also expanding. Cantharidin 0.7% solution (Ycanth), which is applied in the clinic by a health care professional, was approved by the United States Food and Drug Administration (FDA) in 2023 for patients aged 2 years and older (5). The nitric oxide-releasing gel berdazimer 10.3% (Zelsuvmi), which can be applied at home by patients or caregivers, was approved in January 2024 for patients aged 1 year and older (1, 6). These agents differ in mechanism, administration setting, and supporting evidence; therefore, their results should not be extrapolated to Zabalafin Hydrogel. Overall, the literature describes physical, chemical, immunomodulatory, and antiviral approaches, with no universally accepted optimal strategy (4).

Zabalafin Hydrogel: Preparation and Characterization

Zabalafin Hydrogel (Alphyn Biologics, Inc.) is an investigational, botanically derived topical formulation under development for MC and, separately, for atopic dermatitis. It is distinct from berdazimer gel (Zelsuvmi), discussed above, and is produced by a different manufacturer. The clinical evidence for berdazimer gel (1, 6) pertains to Zelsuvmi and is not directly applicable to Zabalafin Hydrogel.

The formulation is based on latex from *Croton lechleri* Müll.Arg. (Euphorbiaceae), the Amazonian “dragon’s blood” tree. According to a patent assigned to the developer, the latex is collected from the wounded trunk, filtered to remove plant debris, and incorporated whole and unfractionated into a water-based hydrogel (7). The latex is described as a complex mixture of alkaloids, lignans, phenolic compounds, proanthocyanidins, and other constituents. The patent defines a reference standard using marker compounds (galocatechin, epigallocatechin, catechin, epicatechin, the alkaloid taspine, and the lignan dimethylcedrusin), each specified at a minimum concentration, together with a polydispersity index of approximately 0.5 to 0.85 (7). Exemplary hydrogels contain approximately 5% to 80% latex by weight, with approximately 40% exemplified, combined with glycerin, phosphate buffers, medium-chain triglycerides, preservatives, and a synthetic polymer-based gelling system, at a pH of approximately 3.0 to 7.0 (7). These formulation and characterization details are derived from publicly available patent and developer information rather than peer-reviewed clinical publications, and the specific composition used in the molluscum trial has not been published. They should therefore be interpreted as a

description of the platform rather than evidence of efficacy or safety.

Proposed Mechanisms and Clinical Development

According to the manufacturer, Zabalafin Hydrogel contains several bioactive compounds intended to act through complementary pathways rather than a single mechanism, an approach the company describes as a multitarget strategy (8). These mechanistic claims currently derive from developer communications rather than peer-reviewed preclinical or clinical publications and should be regarded as proposed mechanisms pending independent confirmation.

For MC specifically, the developer states that the hydrogel is designed to do more than physically remove lesions; it is intended to act directly against the virus, reduce pruritus and inflammation, and address molluscum-associated dermatitis or secondary bacterial infection when present (8). As with the platform’s broader mechanistic claims, these MC-specific effects have been described by the manufacturer but have not yet been reported in a peer-reviewed publication. They should therefore be considered proposed rather than demonstrated effects at this stage.

The developer reports that the Zabalafin platform has an established safety profile based on prior studies and states that this supported advancing the MC program directly into phase 2 development (8, 9). According to company press releases, the MC trial is a randomized, double-blind, placebo-controlled study that enrolled 54 patients aged 6 months and older in Australia, with a 16-week treatment period, a final follow-up visit 2 weeks later, and a primary endpoint of at least 75% lesion clearance (8, 9). Enrollment was reported as complete in March 2026, with topline results anticipated in the third quarter of 2026; at the time of writing, no efficacy, safety, or tolerability outcomes had been publicly reported (8).

This information comes almost entirely from company communications and patent documents rather than peer-reviewed sources, and important gaps remain. No completed trial results, adverse-event data, or head-to-head comparisons with cryotherapy or curettage are currently available for Zabalafin Hydrogel, and its safety and efficacy specifically in refractory MC or in defined pediatric subgroups have not yet been characterized. These limitations preclude conclusions regarding efficacy, safety, or comparative value relative to established therapies at this time.

Potential Role in Persistent or Recurrent Pediatric Disease

A new option would likely be most valuable for childhood disease that is extensive, involves sensitive or difficult-to-treat areas, or persists or recurs despite observation or prior treatment. Destructive approaches, such as cryotherapy and curettage, are effective (4), but they require repeated clinic visits and depend on a child's tolerance for pain. Procedural fear can itself become a barrier to treatment completion. A nondestructive topical therapy, if proven effective and safe, could reduce treatment-related pain and anxiety and lessen the burden of repeated visits. It might also be easier to use when procedures are difficult to perform. It would differ from cantharidin, which requires in-clinic administration, and from other topical agents, whose evidence base cannot be extrapolated to it (5, 6).

These potential advantages remain hypothetical. No peer-reviewed evidence has established the efficacy or safety of Zabalafin Hydrogel in refractory pediatric MC, and outcomes in children with persistent or recurrent disease have not been reported. A nondestructive product is not inherently better tolerated or more effective, and a 16-week treatment course, as used in the ongoing trial (8), would require sustained caregiver adherence. Whether lesions that have failed to respond to other treatments would respond remains unknown.

Research Priorities

Establishing the product's real-world value will require completion and peer-reviewed reporting of the ongoing phase 2 trial and, if supported by the findings, subsequent larger, multicenter phase 3 trials evaluating long-term efficacy and safety across diverse patient populations, including children with persistent or recurrent disease. Future research should assess viral clearance using molecular biomarkers rather than clinical appearance alone; identify patient- or lesion-level characteristics that predict treatment response; directly compare outcomes with established therapies such as cryotherapy and curettage; monitor recurrence rates over longer follow-up periods; evaluate effects on quality of life; and determine cost-effectiveness relative to existing standard-of-care options. These are proposed research directions rather than evidence of therapeutic benefit.

Conclusion

At present, the clinical role of Zabalafin Hydrogel in molluscum contagiosum cannot be determined because efficacy, safety, tolerability, and comparative data have not yet been reported. The available information is limited to a developer-described concept and an ongoing trial, the results of which are pending. Until these results are

available in peer-reviewed form and, if favorable, confirmed in larger, multicenter phase 3 studies, Zabalafin Hydrogel should be considered an investigational agent whose clinical value remains to be established. Clinicians should continue to rely on approved therapies and options supported by established evidence.

Footnotes

AI Use Disclosure: The authors declare that no generative artificial intelligence tools were used in the creation of this article.

Authors' Contribution: Study Concept and Design: L. N. S.; Literature Search and Initial Manuscript Drafting: L. N. S. and T. A.; Critical Scientific Review and Evidence Interpretation: J. A.; Critical Revision for Important Intellectual Content and Discussion Refinement: B. A.; Study Supervision, Overall Guidance, and Final Approval: M. U.; All authors reviewed, edited, and approved the final manuscript and agreed to be accountable for all aspects of the work.

Conflict of Interest Statement: The authors declare no conflicts of interest for this study.

Funding/Support: No funding was received for this study.

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